

REMARKS

Status of the Claims

Claims 5 to 18 and 20 to 25 are pending and under consideration.

Claim rejections under 35 U.S.C. § 103

The Final Office Action rejected claims 9-13 and 22-24 under 35 U.S.C. § 103(a) over Tanaami (US 20010016321) in view of Lehmann (EP 1161984).

The Final Office Action argued that Tanaami teaches a reaction vessel comprising a tubular body having a bottom wall and sidewalls and that the bottom walls and sidewalls form a straight tubular chamber for receiving a liquid and for interacting with a pipetting tip. Based on the disclosure of paragraph [0029] of Tanaami, the Final Office Action further argued that a pipetting tip can be pushed through a rubber plug that seals the top opening of the tube. The Final Office Action argued that a chip shaped carrier having an active surface formed by a plurality of biopolymers is located on the inner surface of the tubular sidewall. The Final Office Action acknowledged that Tanaami does not state that the chip shaped carrier is located in either an opening of a tube side wall or a recess formed within the inner surface of a tube side wall.

The Final Office Action argued that Lehmann discloses a reaction vessel for processing a biological sample contained in a liquid, that the vessel includes a body having a bottom wall, an upper opening and side walls which extend between the bottom wall and the upper opening. The bottom wall and the side walls form a chamber receiving a liquid to be processed. A chip shaped carrier having an active surface is accessible to liquid contained in the chamber. The chips shaped carrier is located in an opening in the sidewall of the tubular body. The Final Office Action argued that it would have been obvious to provide the chip shaped carrier disclosed by Tanaami either within an opening of the tube side wall or within a recess formed in the interior surface of the tube side wall in view of Lehmann. The Final Office Action argued that this would require a minor structural alteration that would be completed in a highly predictable manner.

In response to the Final Office Action, Applicants argued that paragraph [0029] discloses a device wherein the processing chamber is under negative pressure. Applicants further argued that in paragraph [0029] cited by the Examiner, Tanaami teaches that the processing chambers is under negative pressure and that the liquid introduced by a needle through the rubber plug is aspirated through the pre-processing chamber into the processing chamber by negative pressure. Applicants argued that opening the rubber plug

to allow pipetting operations would mean removal of the negative pressure and would render the device disclosed by Tanaami unsuitable for its intended purpose because it would no longer work according to the principle described in paragraph [0029]. Applicants further argued that a needle is not and cannot be assimilated to a pipetting tip and that a pipetting tip cannot pierce a rubber plug and therefore that pipetting operations are not possible with the device disclosed in Tanaami without removing the rubber plug. Applicants argued that the device disclosed in Tanaami comprises a pre-processing part (15) blocking the passage to the processing chamber. The presence of the pre-processing part (15) is required for the device disclosed by Tanaami to work and this pre-processing does not allow pipetting operations in the processing chamber. Applicants argued that pipetting operations in the processing chamber would mean removal/disruption of the pre-processing chamber to allow a pipetting tip to reach the processing chamber and therefore alteration of the principle of operation of the device.

The Advisory Action argued that the device disclosed by Tanaami does not require a mandatory negative pressure to induce fluid flow to the processing chamber and that Tanaami teaches numerous other fluid flow embodiments in paragraphs [0036] to [0039]. The Advisory Action argued that it is certainly within the purview of one for ordinary skill in the art to remove the rubber plug of the device taught by Tanaami, either temporarily or permanently in order to introduce a solution. The Advisory Action further argued that such an action would not interfere with or change the principle of operation of the device taught by Tanaami because said device does not necessarily require the maintenance of an internal negative pressure.

In fact, paragraphs [0036]-[0039] of Tanaami, to which the Advisory Action refers, explicitly disclose only three alternative methods to the method of paragraph [0029]: electrophoresis [0037], diffusion by osmotic pressure [0038] and osmosis [0039]. No other method is described.

It is a technical fact that diffusion by osmotic pressure and osmosis based methods per definition require a membrane through which the liquid is passed. For these osmotic flow based methods to work, a membrane must be present between the rubber plug and the processing chamber. Such a membrane would ineluctably forbid pipetting operations into the processing chamber, and pipetting operations would ineluctably mean either removal or piercing of this membrane which would change the principle of operation of the device being modified. As for electrophoresis techniques, they require an electrode apparatus consisting of a voltage supply, electrodes, buffer, and a support for the buffer to migrate, such as typically a filter paper, cellulose acetate strips, polyacrylamide gel, or a

capillary tube. In paragraph [0037] Tanaami teaches that voltage is applied to and across pre-processing block (15) which *de facto* serves as a support for migration of the liquid toward the processing chamber. In this case, pre-processing block (15) is mandatory and physically bars from pipetting operations in the processing chamber. Removal of pre-processing chamber (15) to allow pipetting operations into the processing chamber would render the device disclosed by Tanaami unsuitable for its intended purpose because it would no longer work according to the principles of operation disclosed by Tanaami.

It is a technical fact that all embodiments of the device disclosed by Tanaami bar from pipetting operations in the processing chamber. As explained above osmosis based techniques require a membrane that does not allow pipetting operations (the pipette tip would destroy the membrane). A device using the osmosis method without membrane or with a pierced membrane would no longer work. As for electrophoresis techniques, they require a support for migration that would not allow pipetting operations either.

In addition, a pre-processing block (15) is required to pre-process fluids that are to be analyzed in the processing chamber. This pre-processing part does not allow pipetting operations in the processing chamber because the pipette tip cannot go through this part without destroying it. Removal of the pre-processing part is not possible either without altering the principle of operation of the device. The Final Office Action and the Advisory Action both failed to address this point. The pre-processing block (15) is never described as an optional or removable part in Tanaami and the Examiner has failed to explain how a person skilled in the art would reasonably, based on an objective reading of Tanaami come to the conclusion that it is optional or that it can be removed without damaging the device. Because of the presence of this pre-processing block (15), it is also a technical fact that modifying the device disclosed by Tanaami to allow pipetting operations by removing the pre-processing block (15) would fundamentally alter its principle of operation to such an extent that it would no longer work according to the teaching of Tanaami. According to Tanaami, this pre-processing block (15) is necessary. Therefore, a person of ordinary skill in the art would not have been motivated by the teaching of Tanaami to modify the device disclosed by Tanaami by removing this pre-processing block (15) to allow pipetting operations. Based on the technical facts available upon objectively reading Tanaami, modifying the device disclosed by Tanaami to arrive at the invention would definitely alter its principle of operation. Consequently, there would be not motivation for the person skilled in the art to modify the device disclosed by Tanaami to allow pipetting operations.

MPEP 2143.02.VI. states that "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being

modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious". And MPEP 2143.02.V states that "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.

This also responds to the Examiner's statement on pages 10 and 11 of the Final Office Action that the person skilled in the art would have substituted the fluid introduction system disclosed in Tanaami with the fluid introduction system of Lehmann. Such substitution would not be possible without completely altering the principle of operation and without rendering said device unsuitable for its intended purpose.

Thus, the person skilled in the art would not have been motivated to modify the device disclosed in Tanaami to enable pipetting operations, because this would require a complete redesign in structure and functions, which would drastically alter its original principle of operation and would render it unsuitable for its intended purpose.

The Office Action concedes that the vessel of the invention also differs from the device disclosed in Tanaami for the reason, the chip shaped carrier is located in an opening of a side wall of said tubular body or in a recess formed in the inner surface of said side wall. The benefits of this special arrangement are described on page 5, line 35 to page 6, line 5 of the patent application as filed:

"This particular location of the chip shaped carrier is advantageous because it allows removing entirely any liquid contained in reaction vessel by a simple pipetting operation during which a pipetting tip is inserted into the vessel until it practically touches the bottom of the vessel. Since the chip shaped carrier and the active surface thereof are not at all in the travel path of the pipetting tip this tip cannot cause any damage of the active surface of the chip shaped carrier."

Clearly, Tanaami neither teaches nor suggests such a feature and its associated benefits.

Further, none of the other prior art of records teaches the benefits of the invention in view of the specific location of the chip in the processing chamber.

Claims 10-18 and 20-25 depend on claim 9 and incorporate all its limitations. The arguments presented above with respect to claim 9 hence also apply to claims 10-18 and 20-28.

In view of the above, reconsideration and withdrawal of the rejection to claims 9-13 and 22-24 under 35 U.S.C. § 103(a) over Tanaami in view of Lehmann is respectfully requested.

The Final Office Action also rejects claim 5 under 35 U.S.C. § 103(a) over Tanaami (US 20010016321) in view of Lehmann (EP 1161984) and Larry (US 4845025).

Claim 5 has common limitations with claim 9 and therefore, the arguments presented above with regard to claim 9 over Tanaami in view of Lehmann also apply to claim 5.

The Final Office Action states that Larry teaches mixing along a predetermined elliptical trajectory. However, Larry does not provide any teaching allowing the person skilled in the art to modify the device disclosed in Tanaami to arrive to the invention in an obvious manner. As explained above, modifying the device disclosed in Tanaami to allow pipetting operations in the processing chamber would completely alter its principle of operation by removing the required osmosis membrane or support for electrophoresis. Also, pipetting operations in the processing chamber would require removal of the pre-processing block and render the device disclosed in Tanaami unsuitable for its intended purpose. MPEP 2143.02.V and MPEP 2143.02.VI. make it clear that the invention cannot be seen as obvious in view of these facts.

Reconsideration and withdrawal of the rejection to claim 5 under 35 U.S.C. § 103(a) over Tanaami (US 20010016321) in view of Lehmann (EP 1161984) and Larry (US 4845025) is therefore respectfully requested.

The Final Office Action also rejects claims 6-8 under 35 U.S.C. § 103(a) over Tanaami (US 20010016321) in view of Lehmann (EP 1161984), Larry (US 4845025) and further Frackleton (US 5133937).

Claims 6-8 depend on claim 5 and incorporate all its limitations. The arguments presented above with respect to claim 5 over Tanaami in view of Lehmann and Larry hence also apply to claims 6-8.

The Office Action states that Frackleton teaches a reaction vessel coupled to a vessel holder that comprises various heat transfer elements. However, Frackleton does not provide any useful teaching allowing the person skilled in the art to modify the device disclosed in Tanaami to arrive to the invention in an obvious manner. As explained above, modifying the device disclosed in Tanaami to allow pipetting operations in the processing chamber would completely alter its principle of operation by suppressing the required osmosis membrane or support for electrophoresis. Also, pipetting operations in the processing chamber would require removal of the pre-processing block and render the device disclosed in Tanaami unsuitable for its intended purpose. MPEP 2143.02.V and MPEP 2143.02.VI. make it clear that the invention cannot be seen as obvious in view of these facts.

Reconsideration and withdrawal of the rejection to claims 6-8 under 35 U.S.C. § 103(a) over Tanaami (US 20010016321) in view of Lehmann (EP 1161984), Larry (US 4845025) and Frackleton (US 5133937) is therefore respectfully requested.

The Office Action also rejects claims 14-16 under 35 U.S.C. § 103(a) over Tanaami (US 20010016321) in view of Lehmann (EP 1161984), Larry (US 4845025) and further Frackleton (US 5133937).

Claims 14-16 depend on claim 9 and incorporate all its limitations. The arguments presented above with respect to claim 9 over Tanaami in view of Lehmann also apply to claims 14-16.

As explained above, neither Larry nor Frackleton would allow the person skilled in the art to arrive to the invention in an obvious manner. In fact, none of these documents provide teaching that would allow modification of the device disclosed in Tanaami to arrive to the invention. Further, as explained above, modifying the device disclosed in Tanaami as stated in the Office Action would not be possible without altering its principle of operation and without rendering it unsuitable for its intended purpose.

Reconsideration and withdrawal of the rejection to claims 14-16 under 35 U.S.C. § 103(a) over Tanaami (US 20010016321) in view of Lehmann (EP 1161984), Larry (US 4845025) and Frackleton (US 5133937) is therefore respectfully requested.

The Final Office Action also rejects claim 25 under 35 U.S.C. § 103(a) over Tanaami (US 20010016321) in view of Lehmann (EP 1161984) as applied to claim 9 and further in view of Mochida (GB 2129551).

Claim 25 depends on claim 9 and incorporate all its limitations. The arguments presented above with respect to claim 9 over Tanaami in view of Lehmann also apply to claim 25.

The Office Action states that Mochida teaches a vessel with barcode labels. However, Mochida does not provide any useful teaching allowing the person skilled in the art to modify the device disclosed in Tanaami to arrive to the invention in an obvious manner. As explained above, modifying the device disclosed in Tanaami to allow pipetting operations in the processing chamber would completely alter its principle of operation by suppressing the required osmosis membrane or support for electrophoresis. Also, pipetting operations in the processing chamber would require removal of the pre-processing part and render the device disclosed in Tanaami unsuitable for its intended purpose. MPEP 2143.02.V and MPEP 2143.02.VI. make it clear that the invention cannot be seen as obvious in view of these facts.

Reconsideration and withdrawal of the rejection to claim 25 under 35 U.S.C. § 103(a) over Tanaami (US 20010016321) in view of Lehmann (EP 1161984) as applied to claim 9 and further in view of Mochida (GB 2129551) is therefore respectfully requested.

CONCLUSIONS

The present Amendment is accompanied with a Request for Continued Examination. The Commissioner is authorized to charge the RCE fee under 37 C.F.R. § 1.17(e) required for this submission to Deposit Account No. 50-0812. In view of the above, Applicants respectfully request the finality of the Final Office Action mailed March 05, 2009 to be withdrawn and the patent application to be allowed.

The shortened statutory period of three months originally set for responding to the Final Office Action expired on June 05, 2009. A two-month extension of time is therefore requested. The extension of time resets the deadline for responding to August 05, 2009. The Commissioner is authorized to charge the corresponding fee under 37 C.F.R. § 1.17(a)(2) to Account No. 50-0812. No other fee is believed to be due at this time, however, the Commissioner is authorized to charge any fee deficiency, or credit any overpayment, to the same deposit account.

If the Examiner believes that a telephone call would expedite prosecution of this application, the Examiner is invited to call the undersigned directly at the number below.

Respectfully submitted,

/Vivien M. Banholzer/

Vivien M. Banholzer (Reg. No. L0508)

Date: July 24, 2009

Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588
Tel. 925-730-8565
Fax 925-225-1128